different --

DR. WEISS: Okay. So we have a motion for something separate than the previous motion, which is a post-market study, and that could be clarified at another time, I assume.

DR. SCHEIN: The purpose is to look for rates of cataract, retinal detachment, treatment for elevated eye pressure, and any other conditions felt appropriate by the FDA.

DR. WEISS: And this -- to clarify for the panel, this would be a new cohort of patients who began enrollment after this was into the marketplace.

DR. SCHEIN: After it's approved, yes.

DR. COLEMAN: I second it.

DR. WEISS: We have a second by Dr. Coleman. Does the agency need any clarification of that before we have a vote? There's a proposal -- a motion --

DR. ROSENTHAL: The agency only -- no, we understand the motion quite clearly. The agency would like to know if there are any specific issues --

DR. SCHEIN: He said cataract, retinal --

DR. ROSENTHAL: Oh, did he? I'm sorry.

DR. SCHEIN: Cataract, retinal detachment.

SPEAKER: Elevated interocular pressure.

DR. SCHEIN: Elevated interocular pressure.

DR. WEISS: Is there any discussion --

DR. ROSENTHAL: And you're happy for us to work it out with the company and our post-market surveillance people.

DR. SCHEIN: Yes.

DR. ROSENTHAL: And possibly members of this panel as homework assignments.

DR. SCHEIN: Yes.

DR. ROSENTHAL: Thank you.

DR. WEISS: Does the panel -- Dr. Macsai.

DR. MACSAI: As a friendly amendment, Dr. Schein, could we add glaucoma to not just elevated interocular pressure?

DR. SCHEIN: Yes.

DR. MACSAI: And is the purpose of this -- clarify for me, because I still got a little confused there earlier. The purpose of this is to see how the

device performs out in the general world?

DR. SCHEIN: Yes. In patient populations that are not strictly selected based on inclusion criteria for a study amongst surgeons- at-large who receive training, to see what the risk profile is.

DR. MACSAI: So this would be surgeons who aren't investigators.

DR. SCHEIN: This would be the actual use of the product after it is approved.

DR. MACSAI: Okay.

DR. WEISS: I just have a question to the agency. Does this meet least burdensome provisions in terms of what you heard?

DR. ROSENTHAL: I think you can recommend what you want to recommend. I would like to get some sense of time though, Dr. Schein.

DR. SCHEIN: Well --

DR. ROSENTHAL: You know, you can do a post-market study for a day, a month, a year, 25 years.

DR. SCHEIN: As some people in the audience know, there was a requirement for those who

received approval for silicone hydrogel extended wear contact lenses to estimate a rate of ulcerative keratitis. That's a different issue, because the time duration is not as important there, but a greater sample size is important, so that study is in 5,000 individuals for a year. I would surmise -- without doing some calculations, I don't want to just make things up off the cuff, that the sample size would be smaller, but the duration a little longer. So I would think in the two to three year range, but with a smaller sample size. There are techniques for working these things out, which are well-known.

DR. ROSENTHAL: Thank you.

DR. WEISS: So we have a second. Is there any other discussion? Otherwise, we'll put it to a vote. All those in favor signify by raising your hand.

(Vote taken.)

MS. THORNTON: Dr. Sugar for, Dr. Bandeen-Roche for, Dr. Schein for, Dr. McMahon for, Matoba for, Bradley for, Mathers for, Ho for, Macsai for, Coleman for.

DR. WEISS: All those who are against, signify by raising your hands.

(Vote taken.)

MS. THORNTON: Grimmett against.

DR. WEISS: Any abstentions? No abstentions. Any other motions? So the motion is passed, 10-1. Any other motions? Dr. Macsai.

DR. MACSAI: As a point of clarification, Dr. Weiss, we talked about all kinds of other things earlier.

DR. WEISS: Yes.

DR. MACSAI: Anterior chamber depth, preoperative endothelial cell count, labeling issues. Am I to assume that all those are in the yea, or do we vote on each one of those?

DR. WEISS: We won't vote on each of them, but what I wanted the panel to do is to bring up any other motion -- any other conditions, and if there are no others, then I will just read from what I scribed, and I would ask Dr. Mathers to fill in anything that I might have missed.

DR. MACSAI: Why don't you read them, and

then we'll see if you missed anything.

DR. WEISS: Okay.

DR. MACSAI: May save time.

DR. WEISS: Okay. So under -- this is going to be a grab-bag because I listed it in each of the -- underneath each of the questions that were posed by FDA. There was the desire for indicating that patients should have a preoperative endothelial cell count prior to having this procedure, demonstrating normal endothelium for age. There was a consideration of serial endothelial cell counts postoperatively. There was no determination made on that particular one, so we might want to put that was a separate condition and have a vote on that.

Preoperative endothelial cell count with normal endothelium for age, I think we can list in the grab-bag with everything else that there was fairly uniform agreement on. I would -- if you would like, Dr. Macsai, because I think you had brought this up, is consideration of serial endothelial cell counts postoperatively. Did you want to raise that as a motion to be voted on or not?

DR. MACSAI: I think I was voted down.

DR. WEISS: Well, you don't -- it's not a vote until we do it now. So do you want to put it forward as a vote, or leave it be as a condition to be voted on, or would you rather it not?

DR. MACSAI: No. I'm comfortable with the preoperative endothelial cell count.

DR. WEISS: There was indication of not implanting in anterior chamber cell depths less than three.

DR. MACSAI: That's correct.

DR. WEISS: That's correct. In terms of with the post-market information, and I will presume that would refer to Dr. Sugar's motion, as well as Dr. Schein's motion, information on the cataract, as well as the specular microscopy. Information indicating that we don't know whether removing or exchanging the lens causes more complications. Information or requesting the Sponsor to give us information whether the axial length measurement is accurate if an IOL is in place. Mandating training. Indication that this is efficacious for reduction, not correction, of

myopia over minus 15. Indication that the IOP may increase if the viscoelastic is not rinsed out. Recommendation that the IOP checked in 4 to 6 hours, and 24 hours. For this particular one, check in 4 to 6 hours and 24 hours. If there's a question on this, we can keep that as a separate motion and vote on that. Was there agreement on that particular one? Dr. Coleman.

DR. COLEMAN: I thought there was only agreement on within 24 hours.

DR. WEISS: So we can take out the 4 to 6 hours. Fine. Dr. Macsai.

DR. MACSAI: I would like to see that 4 to 6 hour recommendation be left in.

DR. WEISS: So if you'd like to see that left in, why don't you put it forward as a separate motion from the grab-bag of motion that everyone is agreeing to and have a vote on it.

DR. MACSAI: Can we?

DR. WEISS: Yes, you can.

DR. MACSAI: Okay. I move that we recommend that in the labeling, we recommend to the

surgeons they check the patient's pressure 4 hours post-op. And I think that that might have been followed by most of those investigators on this study. And the label -- if the Sponsors would like to clarify that, I know that they're not allowed, but I think that's a really good idea.

DR. WEISS: So we have a motion. Check the pressure 4 to 6 hours. Do we have a second of that motion?

DR. COLEMAN: I second it.

DR. WEISS: Can we have a vote. All in favor say aye or raise your hands aye.

(Vote taken.)

DR. WEISS: We have Dr. Macsai, Dr. Coleman, Dr. Grimmett for. All of those against.

(Vote taken.)

DR. WEISS: Dr. Sugar, Dr. Schein, Dr. McMahon, Dr. Matoba, Dr. Ho, Dr. Mathers. All of those abstaining?

(Vote taken.)

DR. WEISS: Dr. Bandeen-Roche and Dr. Bradley. The motion does not pass, so we're going to

include it in the grab-bag. Check IOP in 24 hours. We're going to ask the Sponsor to provide information. Was there -- gonioscopy will be performed at four years, as part of these studies that have been mentioned by Dr. Sugar and Dr. Schein. Dr. Coleman. Well, I'm talking about as part of the post-market studies, you want gonioscopy to be performed, or is this gonioscopy that was already performed that you want the results?

DR. ROSENTHAL: Dr. Weiss, you're talking about post-market evaluation on the IDE cohort. Is that what you're talking about now?

DR. WEISS: I'm bringing up both factors of Dr. Sugar's -- Dr. Coleman had brought up the interest in getting gonioscopy at four years, and I would like to clarify for the agency whether we're talking about gonioscopy for the cohort that was studied, or whether gonioscopy would be done -- Dr. Schein is nodding, so this is from the cohort that was originally studied. That would be satisfactory?

DR. COLEMAN: Yeah. This is for the cohort that was originally studied, but I thought that

that -- that was based on the four years data pre-approval. And we've already passed a condition for --

DR. WEISS: So you're no longer interested in that?

DR. COLEMAN: No. I am interested in it, but I don't see -- you know, it's not a condition, I guess, because it would be approved - - I mean, you're talking if they would do --

DR. WEISS: Well, we're just talking about information gathering as part of the four year specular microscopy. Do you still want gonioscopy? If you don't, we can --

DR. COLEMAN: No, I do.

DR. WEISS: You do. Okay. So we'll include it. It's not a condition --

SPEAKER: It's not for approval.

DR. WEISS: It's not a condition.

DR. COLEMAN: It's not a condition. Okay.

DR. WEISS: We're going to label the -- for labeling -- yes, Sally.

MS. THORNTON: This list that you just

gave, is this -- this is to be collected under one condition called "Additional Information Needed from the Sponsor"?

DR. WEISS: I think it depends on each of -- no. The answer is no.

MS. THORNTON: Well, what is this?

DR. WEISS: I think if you --

DR. MACSAI: These are conditions.

DR. WEISS: It doesn't fulfill one -- these are all separate conditions that there was essentially unanimous agreement on, and they would ordinarily be voted on separately, but in interest of time and because we've discussed them already, they're going to be listed together. Although, the only thing they have in common is the unanimity of the panel's agreement to include these as either labeling or information that's required from the Sponsor, or -- for example, we have something here, "Do Not Implant In Anterior Chamber Depth Less Than 3", and advice to put this in in someone with a normal preoperative endothelial cell count, and these are -- there's all variation here.

MS. THORNTON: Okay. Could we, for the -- in the interest of trying to track this complete motion, could you please -- you're saying some of them are for this group, some of them for that group. Could you vote on the ones that are for the Sponsor to gain additional information, I think for clarity. And then you can say the group of labeling so that it's all -- it's separated. So you can vote on additional information, then vote on labeling issues. Those are separate motions.

DR. MATHERS: This is all the original cohort that we've been deciding now.

DR. WEISS: Yes.

DR. MATHERS: Not the labeling. I'm not sure that we have to go through all these.

DR. WEISS: Well, let's go through each of the -- no, we won't discuss them individually, but --

DR. ROSENTHAL: We need to know what you want done on the original cohort when they come back.

DR. WEISS: Why don't we just handle that then. If you're talking --

DR. ROSENTHAL: We understand the endothelial cell counts at four and five years. We need to know, is there another part of the examination. Do you want gonioscopy performed, do you want pupil size, and some evaluation of glare issues? Those are things which you can have done on your fourth year visit.

DR. WEISS: From what I understand --

DR. ROSENTHAL: Or fifth year visit.

DR. WEISS: From the panel, for the original cohort, the main interest was yearly specular microscopy until which point the agency feels that stabilization has been met. And Dr. Coleman wanted gonioscopy, particularly at four years.

DR. COLEMAN: And peripheral anterior synechiae and pigment deposition.

DR. WEISS: Can you repeat that?

DR. COLEMAN: Peripheral anterior synechiae and pigment deposition.

DR. WEISS: Did you want that yearly, or you wanted that just --

DR. COLEMAN: No, just at four years, or

at some time point.

DR. WEISS: So we -- the panel was only looking for two things, specular microscopy in the original cohort, and gonioscopy. Was there anything else? Dr. Macsai.

DR. MACSAI: Yes. We discussed also when they came back for their four and five year visit, looking at the lens. Dr. Sugar recommended that.

DR. WEISS: Yes, you're right. So specular microscopy and examination of the lens yearly. Is there anything else? Does that satisfy what we're looking at for the cohort?

DR. MACSAI: Yes.

DR. WEISS: Do you need us to vote on that? So can someone put that forward as a motion.

DR. MACSAI: I move that at the four and five year checkup of these patients when we're measuring endothelial cell density, we also ask the Sponsor to perform gonioscopy and examination of the lens, report the data to the FDA for their analysis, and this be done for a minimum of five years to attempt to further establish safety parameters for the

device.

DR. WEISS: Do we have a second of that? Dr. Matoba seconds. Can we have a vote. All those in favor, raise your hand, signify agreement.

(Vote taken.)

MS. THORNTON: Sugar for, Bandeen-Roche for, Schein for, McMahon for, Matoba for, Bradley for, Mathers for, Ho for, Grimmett for, Macsai for, and Coleman for, unanimous.

DR. WEISS: So now with the cohort being handled, we're going to go to labeling issues. One of the labeling issues was to label the stability of the endothelial cell loss as not been documented yet, that long-term information about development of glaucoma is not known. Dr. Coleman had a list since -- I'm going to -- can you read that list for me, Dr. Mathers? Would you be so kind?

DR. MATHERS: Risks greater than -- pressure greater than 25 or increased more than 10 millimeters. And we were going to ask you for clarification on that, but it was --

DR. COLEMAN: Can I look at it?

DR. ROSENTHAL: While you're doing that, can I be sure that you've done the issue of anterior chamber cell -- anterior chamber depth?

DR. WEISS: We listed that.

DR. ROSENTHAL: Okay. So it'll be contraindicated in anterior chambers less than 3 millimeters.

DR. WEISS: Yes.

DR. ROSENTHAL: And you also said an endothelial cell count?

DR. WEISS: Yes, we did. That's endothelial cell count must be normal for age before starting.

DR. ROSENTHAL: Okay. That's all been approved by the panel.

DR. WEISS: Yes.

DR. ROSENTHAL: Thank you.

DR. COLEMAN: There was a precaution that the long-term risk of glaucoma, peripheral anterior synechiae and pigment dispersion are unknown. On page 20 and 18, to change their use of the term "glaucoma" to ocular hypertension and give a definition of what

they called ocular hypertension, their pressure levels, whatever it was. On page 20 and 18 of the labeling, to place it that it was 5 individuals that had pressure greater than 25 or more than a 10 millimeter mercury increase from pre-op. And that's about a 1.4 percent incidence. And on page 14, to change the wording in the second line to talking about flushing out the viscoelastic, that using the cannula through the wound, you may flush viscoelastic from the eye, and this may or may not be adequate for decreasing the risk of elevated eye pressures immediately postoperatively. And then the recommendation, interocular pressure measurements within 24 hours post-op, but that's been covered.

DR. WEISS: Also, Dr. Macsai had mentioned including limbal pathology which prevents you from getting measurements as an exclusion criteria, that data about the incidence of halos, glare be included, that there's also mentioned by others, that there's a learning curve with higher upside down lens rate and cataracts formation in surgeons with less experience. This is more complications on a per-patient than a

per-eye basis was mentioned by Dr. Schein, that this be listed that way. That under "Patient Precautions", pigment dispersion be listed.

Dr. Macsai wanted information about the 65 excluded eyes be included, that the risk of retinal detachment remains unknown, that Dr. Sugar had wanted removal of the phrase indicating that this improves the quality of vision, and having specification as far as what is meant by this, that the brochure have a picture of the device and the positioning.

We have already indicated that the labeling will indicate that there's correction of myopia up to minus 15, and it's for reduction of myopia over minus 15.

Under M.D. labeling, post-op regime using the PMA with Ocuflox and Tobradex, rather than recommending that this must be used in all patients. Indicate that higher myopes had worse results with lower efficacy and higher risk, and the long-term effect on the endothelium is not known for all patients.

It was suggested that under the patient

book, explain what a diopter is. Don't use abbreviations. Also, the affect of the pupil size for this device is not known, and increased IOP may be associated. I think that's already been handled by Dr. Coleman's comments.

Were there any other labeling issues that -- Dr. Matoba.

DR. MATOBA: Well, I previously mentioned that I think risk of endophthalmitis, and possible loss of the eye should be mentioned under possible adverse events. And the term "phakic IOL", or interocular lens was used in the patient information sheet, and that should be clarified. And alternative treatment should be listed more specifically. It's sort of mentioned in passing in the introduction, but it should be listed specifically.

DR. BRADLEY: Also, Jayne, the suggestion was made that implantable contact lens be -- that name be changed presumably in the device.

DR. WEISS: Well, I understood from the agency that that's not something that we would get involved in. Ralph, are we getting involved in names?

I guess we're not getting involved in names.

DR. ROSENTHAL: You can recommend whatever you'd like to recommend, and we will --

DR. WEISS: So what -- is that --

DR. ROSENTHAL: -- act accordingly if we feel that --

DR. WEISS: What would you like to say specifically as far as that goes?

DR. BRADLEY: I think it should be described to the patient in an accurate way, and if the FDA deems that contact lens is misleading, which some of us on the panel believe, then that should be changed.

DR. WEISS: So we could have a better description of what is meant in this case of a contact lens in the labeling. I don't know if we list it, but we should list that the effect of pupil size is not known. I think I mentioned that. I did mention that. Dr. McMahon.

DR. McMAHON: I think the intent of the comment was, is not to explain what a contact lens is, but that the word "contact lens" is misrepresentative

of what this device is. And the panel recommends that that term be eliminated from the title of the device, and from labeling.

DR. WEISS: I think the -- does the panel sort of -- is there consensus on that statement? I see head nods which will -- so there's consensus that this -- that wording is deceptive, and we would leave it up to the FDA to come up with better wording. What was that?

DR. MATHERS: Explain possible need for chronic pressure medications.

DR. WEISS: Was that included in your list of things?

DR. MATHERS: You mentioned it later.

DR. COLEMAN: That's for the patient labeling.

DR. MATHERS: Yeah.

DR. COLEMAN: That was for patient labeling, just so they would be aware that they might need medications to control the interocular pressure.

DR. WEISS: Dr. Macsai.

DR. MACSAI: I'd like to make a motion

that we approve the inclusion of all the labeling issues, for the patient booklet, for the surgeon booklet, all the training issues, all the restrictions, all the caveats that Dr. Weiss has gone through over the past 15 minutes, as part of our conditions of approval.

DR. WEISS: Do I have a second for that?

DR. BRADLEY: Second.

DR. WEISS: So we will then put that to a vote. All of those in favor raise your hand.

(Vote taken.)

MS. THORNTON: Dr. Sugar for, Dr. Bandeen-Roche for, Dr. Schein for, Dr. McMahon for, Matoba for, Bradley for, Mathers for, Ho for, Grimmett for, Macsai for. That's it, 10 for.

DR. WEISS: So we have -- the motion has passed so --

MS. THORNTON: No, then there is the vote for against. One against.

DR. WEISS: Sorry. One against. Dr. Coleman against. Sorry. And any abstentions?

MS. THORNTON: We have 11 votes.

DR. WEISS: So the motion passes. That's the labeling motion. So at this point, we will then go -- are there any other motions? Otherwise, we will vote on -- any other conditions? Otherwise, we'll vote on the main motion.

SPEAKER: We did. That was the main motion, wasn't it?

DR. WEISS: No, those were the -- that was labeling.

DR. COLEMAN: Can I change my vote then? I voted for the labeling. Sorry.

DR. WEISS: The transcript can reflect that Dr. Coleman would like to change her vote on labeling. Now that we've reflected that, we'll go on. Are there any other conditions? If there are no other conditions, then we will vote on the main motion, which was put forward initially, the very first thing that was put forward.

MS. THORNTON: Approvable with conditions.

DR. WEISS: Which is approvable of this PMA with conditions, which were already voted on. So all of those in favor -- Dr. Mathers, are you --

DR. MATHERS: This is approval -- this is not a conditional approval. This is approval with conditions.

DR. WEISS: We vote on the -- what we do is we make the main motion, and then we list all the conditions, vote on the conditions, and we then go back to the main motion which has included all these conditions. So we know what the conditions are because we voted on them. Now we're going back to the main motion, which will be the last vote, I hope. Having said that, we're going to vote on the main motion. Can we have a vote. All of those in favor, can you raise your hand.

(Vote taken.)

DR. WEISS: Dr. Sugar is in favor, Dr. Schein, Dr. McMahon, Dr. Matoba, Dr. Bradley, Dr. Ho, Dr. Grimmett, Dr. Macsai are in favor of the motion. Those who are opposed to the motion. Dr. Bandeen-Roche and Dr. Mathers, and Dr. Coleman are opposed to the motion. And those -- anyone abstaining? The motion has passed, and --

MS. THORNTON: Eight to three.

DR. WEISS: And this PMA is approved --

MS. THORNTON: Approvable with conditions.

DR. WEISS: Approvable with conditions. And then I'd like to poll the panel members as to why they had the vote they did. Dr. Coleman.

DR. COLEMAN: I voted against the motion because I felt although there is reasonable assurance of efficacy, I was not comfortable with the reasonable assurance of safety based on glaucoma and angle morphology.

DR. WEISS: Dr. Macsai.

DR. MACSAI: I voted in favor of approval with conditions due to the fact that I felt the efficacy of this device was significantly proven by the sponsors. This device appeared to have a lower incidence of higher order aberrations, and complications involved in operating on the cornea and the visual axis. This device is removable. I do, however, caution that despite the percent hexagonality, and coefficient of variation of the endothelial cell counts appearing to be acceptable, the percent of endothelial cell loss, which would

establish safety, is not determined for this device; and, therefore, post-market surveillance will be required.

DR. WEISS: Dr. Grimmett.

DR. GRIMMETT: Dr. Grimmett voted approval with conditions for similar reasons to Dr. Macsai.

DR. HO: Allen Ho. I voted approvable with conditions. I think the data presented clearly show efficacy and reasonable safety. I'm struck by the lack of visually significant complications in 500 surgeries in this group of at-risk eyes, but I do believe that there is a small chance of a worst case scenario that is below the detection of the design of this current study. And, therefore, I support the surveillance.

DR. WEISS: Dr. Mathers.

DR. MATHERS: I voted against the motion. I believe the device demonstrates excellent efficacy, and in the short term, reasonable safety. But I believe that the data does not support the use of this device in the patient population so described, because of long-term risks of corneal decompensation.

DR. BRADLEY: Dr. Bradley. Yeah, I voted for this motion. I think the device established itself as effective. The concerns about safety raised by the panel, I think will probably best be answered by this potentially larger and post-market study that we've suggested. And I think if the concerns of the panel regarding safety are shown to be true in that post-market study, I think the product will probably be removed from the market.

DR. WEISS: Dr. Matoba.

DR. MATOBA: I voted that the -- in favor of approvable with conditions, because I believe the device has been shown to be reasonably safe and efficacious. However, I am philosophically opposed to the concept of interocular procedures for patients in the range of myopia minus 3 to 4 or 5.

DR. WEISS: Dr. McMahon.

DR. McMAHON: Dr. McMahon. I'd like to congratulate the Sponsor on a well done study for -- a well done presentation of both the data and the presentation today for what otherwise is a very complicated project, and you're to be congratulated.

I've waffled through the day with regard to my vote for approvability, approvable. And I think with the reassurances that the Sponsor will look at the follow-up data in a responsible manner, I voted that way. And hopefully, this will turn out for the best for all of us.

DR. WEISS: Dr. Schein.

DR. SCHEIN: I voted for approvable with conditions, feeling that the data was sound for efficacy. I voiced my concerns about safety. The nature of the device and its intention does not allow safety to be evaluated in a pre-market setting, and if we were to deny this kind of study, it would stifle all innovation. And I think the post-market surveillance gives us adequate comfort.

The last comment I'd like to make is to encourage the FDA to request control groups for these studies. They do not need to perform a randomized clinical trial, but it's not difficult to get control groups matched to age and for Dr. Barrett to look for some of these outcomes.

DR. WEISS: Dr. Bandeen-Roche.

DR. BANDEEN-ROCHE: I voted against the motion because to vote for it, I would have had to conclude that the data set before us gave me a reasonable assurance of safety and efficacy. While I was reasonably convinced of efficacy for reasons I've already described, the data did not meet my threshold for reasonable assurance of safety; that is, I agree with the Sponsor that there is a suggestion of stability, but not yet a reasonable assurance interim. My clinical colleagues indicated to me that without stability, there would be a safety concern. And finally, I would conclude for a reasonable assurance of safety with further data of the sort that we've talked about, panning out in the way everyone would hope.

DR. WEISS: Dr. Sugar.

DR. SUGAR: I voted for approval of the motion. I feel that the efficacy has been well demonstrated, the safety remains a concern, and longer-term data will help assure that. I think at the present time, it is -- appears to be reasonably safe and, therefore, approvable.

DR. WEISS: Mr. Crompton.

MR. CROMPTON: I'd just like to congratulate the Sponsor on an excellent presentation, and it was a long day, tough day. And the panel, for your very, very thorough deliberations today. It really does help industry, and the FDA, of course. And Sally, great job. Thank you.

DR. WEISS: Sally Thornton has a few additional comments before we adjourn.

MS. THORNTON: Just to let you all know that the November 7th panel meeting that was tentatively scheduled, has been cancelled. And shortly, I hope the schedule for the next meetings will be up on the web for 2004. They will be on the hotline very shortly too. I want to thank the panel --

DR. ROSENTHAL: May I just make one comment, that the cancellation of the November whatever day it was, 7th panel.

MS. THORNTON: Yes.

DR. ROSENTHAL: Was made with the agreement of the FDA and the Sponsor.

DR. WEISS: Okay.

MS. THORNTON: I just wanted to thank the panel for their perseverance through a very difficult and complicated application. I appreciate their cooperation to stay and work with us all the way through passed our time. Thank you. And that's all I have.

DR. WEISS: Thank you. The meeting is adjourned.

(Whereupon, the proceedings in the above-entitled matter went off the record at 5:58 p.m)